Adopted	Rejected

COMMITTEE REPORT

YES: 13
NO: 10

MR. SPEAKER:

Your Committee on ***Ways and Means*** *, to which was referred Engrossed Senate Bill 231 , has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill* ***be amended*** *as follows:*

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 16-18-2-32.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 32.5. "Average wholesale price", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-2.**

SECTION 2. IC 16-18-2-143, AS AMENDED BY P.L.14-2000, SECTION 43, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 143. (a) "Fund", for purposes of IC 16-26-2, has the meaning set forth in IC 16-26-2-2.

(b) **"Fund", for purposes of IC 16-42.5-8, has the meaning set forth in IC 16-42.5-8-1.**

(c) "Fund", for purposes of IC 16-46-5, has the meaning set forth in IC 16-46-5-3.

SECTION 3. IC 16-18-2-197.5 IS ADDED TO THE INDIANA

CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 197.5. "Labeler", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-3.**

SECTION 4. IC 16-18-2-216 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 216. (a) "Manufacturer", for purposes of IC 16-42-19, ~~and~~ IC 16-42-21, **and IC 16-42.5,** means a person who by compounding, cultivating, harvesting, mixing, or other process produces or prepares legend drugs. The term includes a person who:

(1) prepares legend drugs in dosage forms by mixing, compounding, encapsulating, entableting, or other process; or

(2) packages or repackages legend drugs.

(b) The term does not include pharmacists or practitioners (as defined in section 288(a) and 288(c) of this chapter) in the practice of their profession.

SECTION 5. IC 16-18-2-318.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 318.5. "Retail pharmacy", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-4.**

SECTION 6. IC 16-18-2-320.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 320.8. "Rx program", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-5.**

SECTION 7. IC 16-42.5 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]:

ARTICLE 42.5. FAIR PRICING FOR PRESCRIPTION DRUGS

Chapter 1. Definitions

Sec. 1. The definitions in this chapter apply throughout this article.

Sec. 2. "Average wholesale price" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

Sec. 3. "Labeler" means a person or an entity that:

(1) receives prescription drugs from a manufacturer or wholesaler;

(2) repackages those drugs for later retail sale; and

(3) has a labeler code from the federal Food and Drug Administration under 21 CFR 207.20.

Sec. 4. "Retail pharmacy" means a retail pharmacy or another business that is licensed to dispense prescription drugs in this state and that dispenses drugs covered by a rebate agreement under the Rx program.

Sec. 5. "Rx program" means the Rx program established by IC 16-42.5-2-1.

Chapter 2. Establishment of Rx Program; General Provisions

Sec. 1. The Rx program is established to help provide discounted prescription drug prices to uninsured residents of Indiana.

Sec. 2. (a) Residents of Indiana are eligible to participate in the Rx program if they do not have prescription drug coverage under any:

(1) health insurance plan; or

(2) federal, state, or local public assistance program.

(b) The state department shall establish simplified procedures for determining eligibility and issuing Rx program enrollment cards to eligible residents.

(c) The state department shall undertake outreach efforts to build public awareness of the Rx program and maximize enrollment by eligible residents.

(d) The state department may adjust the requirements and terms of the Rx program to accommodate any new federally funded prescription drug program.

Sec. 3. The state department may submit a report on the enrollment and financial status of the Rx program to the legislative council before January 1 of each year.

Sec. 4. The state department may adopt rules under IC 4-22-2 to implement this article.

Sec. 5. The state department may do the following in implementing the Rx program:

(1) Coordinate with other governmental programs.

(2) Take actions to enhance efficiency.

(3) Maximize the benefits of the Rx program and other governmental programs, including provision of the benefits of the Rx program to the beneficiaries of other state programs.

Sec. 6. The state department may apply for any waiver of federal law, rule, or regulation necessary to implement the provisions of this article.

Chapter 3. Requirements of Drug Manufacturers and Labelers

Sec. 1. (a) A drug manufacturer or labeler that sells prescription drugs in Indiana through any state funded or state operated program may enter into a rebate agreement with the state department for the Rx program. Participation in this program is voluntary for the drug manufacturers or labelers.

(b) The rebate agreement voluntarily entered into under this chapter must require the manufacturer or labeler to make rebate payments to the state each calendar quarter according to a schedule established by the state department.

Sec. 2. (a) The state department may consider the amount of the rebate voluntarily provided by a manufacturer or labeler in accordance with this chapter.

(b) When negotiating the amount of the rebate, the state department may consider the following:

(1) The average wholesale price of prescription drugs.

(2) Any other information on prescription drug prices and price discounts, including information provided by the drug manufacturer or labeler.

(c) If the state department and a drug manufacturer or labeler fail to reach agreement on the terms of a voluntary rebate agreement, the state department may prompt a review of the prescription drug component of the state Medicaid program for the dispensing of prescription drugs provided by the manufacturer or labeler, as described in section 4 of this chapter.

(d) Any rebate established under this chapter shall take effect as soon as is reasonably possible.

Sec. 3. The following information is a public record (as defined in IC 5-14-3-2):

(1) The name of each manufacturer or labeler participating in the program.

(2) The terms of the voluntary rebate agreements entered into by a manufacturer or labeler and the state department.

Sec. 4. The state department may prompt a review on a case by case basis of the prescription drug component of the state Medicaid

program, as permitted by law, for the dispensing by physicians of prescription drugs provided by manufacturers and labelers that do not enter into voluntary rebate agreements with the state department. The state department shall adopt rules under IC 4-22-2 to carry out its responsibilities under this chapter.

Chapter 4. Calculation of Discount Price

Sec. 1. The state department shall establish discounted prices at which a retail pharmacy must offer prescription drugs covered by a rebate agreement and sold to Rx program participants and shall promote the use of efficacious and reduced cost drugs, taking into consideration the following:

(1) Reduced prices for state and federally capped drug programs.

(2) Differential dispensing fees.

(3) Administrative overhead.

(4) Incentive payments.

Sec. 2. The state department shall use the following formulas to compute the discount prices described in section 1 of this chapter:

(1) Beginning July 1, 2001, and ending December 31, 2001:

STEP ONE: Determine the average wholesale price.

STEP TWO: Subtract six percent (6%) of the wholesale price.

STEP THREE: Add the dispensing fee provided under the state Medicaid program.

(2) After December 31, 2001:

STEP ONE: Use the prices calculated under subdivision (1).

STEP TWO: Subtract the rebate paid by the state to a retail pharmacy.

Chapter 5. Sale of Prescription Drugs at Discounted Prices

Sec. 1. (a) Beginning July 1, 2002, a retail pharmacy may not charge more than the amount computed by the state department under IC 16-42.5-4-2(2) for drugs covered by the Rx program and sold to Rx program participants.

(b) The state department shall specify the discounted price levels.

(c) In determining the discounted price levels, the state department may consider an average of all rebates weighted by

sales of drugs subject to these rebates over the most recent twelve (12) month period for which the information is available.

Chapter 6. Operation of the Rx Program

Sec. 1. (a) The Indiana board of pharmacy established by IC 25-26-13-3 shall adopt rules requiring disclosure by retail pharmacies to Rx program participants of the amount of savings provided by the Rx program.

(b) The rules adopted under subsection (a) must consider and protect information that is proprietary in nature.

Sec. 2. (a) A retail pharmacy shall submit claims to the state department to enable the state department to verify the amounts charged to Rx program participants.

(b) The state department may not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx program.

Sec. 3. (a) On a weekly basis, the state department shall:

(1) reimburse a retail pharmacy for discounted prices provided to Rx program participants by the retail pharmacy; and

(2) pay a retail pharmacy professional fee set by the state department for each prescription dispensed by the retail pharmacy to Rx program participants.

(b) Unless a different amount is set by the state department under subsection (a), the professional fee shall be three dollars ($3) per prescription.

Sec. 4. The state department shall collect from each retail pharmacy utilization data necessary to calculate the amount of the rebate from a manufacturer or labeler, including statistics concerning the sale of prescription drugs to Rx program participants and other customers.

Chapter 7. Discrepancies in Rebate Amounts

Sec. 1. Discrepancies in rebate amounts must be resolved using the process established in this chapter.

Sec. 2. (a) If the manufacturer or labeler rebates less than the amount claimed by a retail pharmacy, resulting in a discrepancy that favors the manufacturer or labeler, the state department, at the state department's expense, may hire a mutually agreed upon independent auditor to conduct an audit to verify the accuracy of

the data supplied by the manufacturer or labeler concerning the amount of the rebate.

(b) If a discrepancy still exists following an audit by the independent auditor hired by the state department under subsection (a), the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the state department for any additional rebate amount due.

Sec. 3. (a) If the manufacturer or labeler rebates more than the amount claimed by a retail pharmacy, resulting in a discrepancy against the interest of the manufacturer or labeler, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed upon independent auditor to verify the accuracy of the data supplied to the state department regarding the manufacturer's or labeler's rebate amount.

(b) If a discrepancy still exists following an audit by the independent auditor hired by the manufacturer or labeler under subsection (a), the state department shall:

(1) justify the reason for the discrepancy; or

(2) before reimbursing the retail pharmacy the amount claimed, refund to the manufacturer or labeler any excess rebate payment made by the manufacturer or labeler.

Sec. 4. Following the procedures established in sections 2 and 3 of this chapter, either the state department or the manufacturer or labeler may request a hearing under IC 4-21.5.

Chapter 8. Rx Dedicated Fund

Sec. 1. As used in this chapter, "fund" refers to the Rx dedicated fund established by section 2 of this chapter.

Sec. 2. (a) The Rx dedicated fund is established. The fund consists of:

(1) revenue from manufacturers and labelers who pay voluntary rebates; and

(2) any appropriations or allocations to the fund.

(b) The purpose of the fund is to reimburse retail pharmacies for discounted prices provided by the pharmacies to Rx program participants. The fund shall be administered by the state department.

(c) The expenses of administering the fund shall be paid from money in the fund.

(d) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested. Interest that accrues from these investments shall be deposited in the fund.

(e) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

Chapter 9. Terms of Rebate Agreement

Sec. 1. (a) A rebate agreement entered into under IC 16-42.5-3-1 must include a verification by the manufacturer or labeler that the price negotiated in the rebate agreement complies with this article.

(b) The state department may perform an audit of any manufacturer or labeler that has entered into a voluntary rebate agreement to determine whether the manufacturer or labeler complied with subsection (a). The state department may contract with a certified public accountant to carry out the state department's duties under this subsection. A manufacturer or labeler shall provide information that the state department may reasonably require to enable the state department to determine whether the manufacturer or labeler is in compliance with this chapter.

(c) If the state department or its agent determines that a manufacturer or labeler has not complied with subsection (a), the state department shall require the manufacturer or labeler to do the following:

(1) Refund to the state department the difference between the price offered to the state by the voluntary rebate agreement and the lowest price agreed to by the manufacturer or labeler under IC 16-42.5-3.

(2) Promptly pay the costs of the audit.

(d) The state may hire counsel to collect any amount under subsection (c), including attorney's fees and the cost of collection, that is not promptly paid.

(e) The state department shall deposit any money collected under subsection (c) into the Rx dedicated fund.".

Page 1, delete lines 1 through 6.

Page 1, line 10, delete "Order" and insert "**Order, Individually Owned,**".

Page 2, line 7, after "2." insert "**As used in this chapter,**

"individually owned pharmacy" means a pharmacy located in Indiana that is owned by:

(1) an individual;

(2) a sole proprietorship;

(3) a partnership;

(4) an association;

(5) a fiduciary;

(6) a corporation;

(7) a limited liability company; or

(8) any other business entity;

that does not own more than three (3) pharmacies in Indiana.

Sec. 3.".

Page 2, line 14, delete "3." and insert "**4.**".

Page 2, line 17, delete "4." and insert "**5.**".

Page 2, line 19, delete "5." and insert "**6.**".

Page 2, line 20, delete "order" and insert "**order, individually owned,**".

Page 2, line 22, delete "not:" and insert "**not**".

Page 2, line 23, delete "(1)".

Page 2, run in lines 22 through 23.

Page 2, line 25, delete "coverage; or" and insert "**coverage.**".

Page 2, delete lines 26 through 30.

Page 2, line 31, delete "from an", begin a new paragraph, and insert: "**(c) An**".

Page 2, line 34, delete "(a)." and insert "**(a) may do so at the same level of copayment as a pharmacy designated in subsection (a).**".

Page 2, after line 34, begin a new paragraph and insert:

"**Sec. 7. Nothing in this chapter requires an insurer to**

contract with a mail order, an individually owned, or an Internet based pharmacy in Indiana.".

Renumber all SECTIONS consecutively.

(Reference is to ESB 231 as printed March 22, 2001.)

and when so amended that said bill do pass.

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Representative Bauer